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February 8, 2022

VIA ECF

The Honorable Thomas Vanaskie
Special Discovery Master
Stevens & Lee
1500 Market Street, East Tower, 18th Floor
Philadelphia, PA 19103

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, Case No. 1:19-md-02875-RBK-KW

Dear Judge Vanaskie:

The ZHP Parties submit this letter brief to provide additional authorities demonstrating that document ECF 1189, Ex. CC, is not a publicly available document and therefore should not be de-designated in whole or in part.

INTRODUCTION AND SUMMARY OF ARGUMENT

ECF 1189, Ex. CC, is the Final GMP Inspection Report from a joint inspection by the European Union drug regulatory authorities, the European Medicines Agency and the European Directorate for the Quality of Medicines & Healthcare (hereinafter

"EMA" and "EDQM"), of ZHP's Chuannan and Xunqiao facilities in China (the "GMP Report" or "Report").

The GMP Report contains sensitive commercial and proprietary information concerning numerous API products produced at the inspected facilities, including the chemical structure of the APIs, internal product codes and the physical location (e.g., the workshop identifier or production area) where the API is produced.

The Report also contains detailed descriptions of the internal processes and procedures employed by ZHP in its research and production operations, comments and evaluations from the regulators regarding technical and procedural aspects of the drug manufacturing, quality control, maintenance and other internal processes and procedures in the inspected facilities. The inspectors' review and sampling of particular batches of product, their careful consideration of specific technical processes and equipment, process development and product manufacture pervade their Report. All of this information is sensitive commercial information of interest and value to ZHP's competitors, is not shared with them by the company, and, if disseminated, would provide ZHP's competitors with confidential and highly sensitive information they do not have about ZHP's API and finished dose manufacturing operations.

Moreover, as shown below, the EMA's own regulations provide complete confidentiality and non-public access to the GMP Report.

ARGUMENT

I. The EMA Has Designated GMP Reports as Non-Public Documents.

The Court should maintain the Restricted Confidential designation of the GMP Report because the European Parliament's Regulation (EC) No. 1049/2001, as incorporated into the EMA's own guidelines relating to public access to its documents, precludes public access to its GMP inspection reports.

The EMA maintains a highly detailed policy regarding public access to EMA documents. The *European Medicines Agency Policy on Access to Documents*, Policy/0043 provides the controlling directives for public access to EMA documents. *See* Policy/0043 attached hereto as Exhibit A. The policy has been in effect since at least 2010, with the most recent revision adopted in October 2018. *Id*. Although Policy/0043 expresses a goal of "[o]penness and transparency" for "the widest possible access to the documents [generated by the agency]…", it also repeatedly underscores that "certain public and private interests, such as …the commercial interests of a natural or legal person, shall be protected by way of exceptions in line with the provisions of Regulation (EC) No. 1049/2001." *Id*. at

p. 1. Policy/0043 also states that "EU Institutions and Agencies are entitled to protect their internal consultations and deliberations where necessary to carry out their tasks." *Id*.

Section 4.1.1 of Policy/0043 provides:

> Whilst providing adequate protection of commercial confidential information, personal data and other conflicting interests as identified ..., access to a requested document will be denied only if one of the exceptions listed in Article 4 of Regulation (EC) No. 1049/2001 will be considered applicable.

See Ex. A at p. 3.

Article 4 of Regulation (EC) No. 1049/2001 provides that public access to certain documents "shall be refused by virtue of application of one of the following exceptions":

> 2. EMA shall refuse access to a document where it determines that disclosure would be likely to undermine the protection of:
>
> a) commercial interests of a natural or legal person, including intellectual property,
>
> * * *
>
> c) the purpose of inspections, investigations and audits,

See Regulation (EC) No. 1049/2001, as reprinted in the Annex to Ex. A.

In conjunction with Policy/0043 and Regulation (EC) NO. 1049/2001, the EMA issued a document titled "*Output of the European Medicines Agency policy on access to documents related to medicinal products for human and veterinary use*" EMA/127362/2006 Rev. 1 (hereinafter the "Output Chart"), a fifty-eight (58) page chart that pre-designates public access designations for many categories of the agency's documents. *See* Output Chart attached as Exhibit B. For many categories of documents on the Output Chart, the designated documents are "releasable" and public access is allowed. *Id*. Electronic searches of the EMA public databases reflect tens if not hundreds of thousands of publicly available documents. The GMP Report relating to the inspection of the ZHP Parties' facilities is not among them, however.

Section 1.1 of the Output Chart contains the following entries related to GMP Reports such as the one at issue in ECF 1189, Ex. CC:

Document type[1]	Thirdparty document[2]	Classification[3]	Access[4]	Reference[5]	Additional justification[6]	Need for redaction of document prior to disclosure[7]
GXP (GMP, GCP, GLP, PhV) Inspection Reports – inspections requested by EMA scientific committees and coordinated by EMA	No, once final and received by EMA	Non-R	No	Art.4.2. 3rd indent		Not applicable
GXP (GMP, GCP, GLP, PhV) Inspection Reports – inspections carried out by NCAs under their national inspection programmes	Yes	Non-R	No	Art. 4.2. 3rd indent		Not applicable
GXP (GMP, GCP, GLP, PhV) Inspection Reports –inspections conducted by third parties (non-EU countries or international organisations)	Yes	Non-R	No	Art. 4.2. 3rd indent		Not applicable

Ex. B at pp. 15-16. The GMP Report at issue here falls within the second category of GMP inspection reports in the chart above: "Inspections carried out by NCAs under their national inspection programmes". NCAs, or National Competent Authorities of EU Member States, are the recognized and approved EU partner agencies and experts from EU nations that work closely with the EMA and the EU regulatory system to maximize cooperation and ensure the European medicines regulatory network functions efficiently. *See generally, "National Competent Authorities," https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human*, attached as Exhibit C. The EMA and NCAs collaborate to maintain a close international cooperation between pharmaceutical inspection authorities in the field of GMP. *Id*. The 2018 GMP inspection that is the subject of the ZHP Parties' GMP Report was conducted by,

among others, inspectors from the Italian Medicines Agency (Italy), Agencia Espanola de Meicamentos Y Productos Sanitarios (Spain), and a scientific expert from the Federal Institute for Drugs and Medical Devices, BfArM (Germany). These are all EMA-approved NCAs.

As reflected in the EMA Output Chart, the EMA explicitly designates GMP Inspection Reports in all categories as "Non-R" (non-releasable) and "No" public access documents. Ex. B. at pp. 15-16, 58. The Output Chart further references the Article 4.2.3rd indent exception to public access to such materials as the basis for withholding their dissemination: "The Agency shall refuse access to a document where disclosure would undermine the protection of the purpose of inspections, investigations and audits." Ex. B at pp. 15-16; 58. Additionally, the Output Chart reflects the EMA's intention that GMP Reports should not be made publicly available even if they are subject to redaction. *See* Ex. B, pp. 15-16, column 7.

It would be inappropriate for this Court to order the de-designation and public release of the GMP Report in direct contravention of the clearly expressed intention of the EMA to maintain GMP inspection reports as non-public documents. The EMA made, and published, the decision to restrict public access to GMP reports in order to protect the integrity and effectiveness of such inspections. Courts consistently uphold the deference afforded to an agency in the interpretation of

statutes administered by the agency, and observe even greater deference to an agency's interpretation and application of the agency's administrative regulations. *See Udall v. Tallman*, 380 U.S. 1, 16 (1965) (holding that while Courts give great deference to the interpretation applied to a statute by the agency charged with its administration, "when the construction of an administrative regulation rather than a statute is in issue, deference is even more clearly in order."); *State of Vermont v. Thomas*, 850 F.2d 99, 102 (2d Cir. 1988) ("when the Administrator's interpretation of his own regulations is at issue, 'deference is even more clearly in order.'"). Research has located no case law in which a court has ordered the public release of EMA's GMP inspection reports. Accordingly, the Court should maintain the Restricted Confidential status and designation of ECF 1189, Ex. CC.

II. Plaintiffs Cannot Establish an Overriding Public Interest in Disclosure.

Although Policy/0043 contemplates accessibility of certain categories of EMA documents, the Policy explicitly considers and limits accessibility to protect the confidentiality of the agency's own work as well as commercially proprietary, confidential and sensitive information of the companies whose facilities are subject to inspection. Ex. A at p. 4. The Policy defines "commercial confidential information" as "any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive

position of the owner of the information." *Id*. Policy/0043 further notes that in the case of documents containing information of commercial interest, "EMA has to strike the balance between the right of the requester to gain access to documents and the interest of industry to have commercial confidential information duly protected." *Id*.

Policy/0043 also reflects the EMA's intention that the databases of documents it currently makes publicly available are of sufficient scope and breadth to satisfy the EMA's obligation of public access:

> EMA considers that the various electronic document databases and systems currently made publicly available by EMA effectively enable the citizens to exercise the rights given to them by Regulation (EC) No. 1049/2011, as required by Article 73 of Regulation (EC) No. 726/2004 and Articles 2(4) and 11 of Regulation (EC) No. 1049/2001.

Ex. A at p. 7.

That GMP reports generally, and the Report at issue here, are not publicly available through one of the existing EMA databases reflects the agency's determination that the Report is not a publicly accessible document. Likewise, Policy/0043 affirms the EMA's commitment to ensuring "the protection of commercial confidential information, personal data, and other conflicting interests". *Id*. at 7. Although the applicable exceptions to public accessibility provide an avenue

for disclosure of documents by the EMA where "there is an overriding public interest in disclosure," Plaintiffs in the instant case cannot demonstrate such an overriding public interest to defeat the EMA's unequivocal proscription against disclosure of the Report. *See* Regulation (EC) No. 1049/2001, attached as Annex to Ex. A at p. 9. To the contrary, the EMA's interest in protecting the integrity of inspections, investigations and audits, as well as its commitment to preserving the confidentiality of personal and company commercial information shared with the EMA and NCAs during inspections outweighs any public interest in making this type of document publicly available. *See* Ex. A at 1 and Annex at p. 9.

As Plaintiffs themselves are aware, documents relating to the detection of impurities in Valsartan API are and have been publicly available through EMA and other regulatory agency reports worldwide, and in an abundance of media feature articles and special reports. Moreover, throughout this litigation numerous documents have been produced in discovery by the ZHP Parties that do not carry a restricted confidential designation and which afford Plaintiffs the opportunity to publicly disseminate information about ZHP's two China plants that produced Valsartan API and its finished dose products. The Plaintiffs also, early in this litigation, submitted a FOIA request to the FDA and received in exchange a wealth of information regarding issues relating to Valsartan and the recall, all of which have

no restricted confidential designations. With an abundance of information already at their fingertips, Plaintiffs cannot articulate any valid reason for disregarding the EMA's clearly articulated view that the Report, quite simply, is not a document permitted public dissemination. *See* Ex. B at pp. 15-16.

For these reasons, the Court should maintain ECF 1189, Ex. CC, as a Restricted Confidential document.

III. The Report is Not Available to Plaintiffs Through An EMA Public Information Request.

Since at least October 4, 2018, non-EU citizens or entities have been precluded from submitting applications for access to documents. *See* Ex. A at p. 4 ("EMA is no longer in a position to process access to documents requests issued from outside the EU"). Even were Plaintiffs to file an application for access to the GMP Report pursuant to Regulation (EC) No. 1049/2001, the EMA will refuse to process the request. *Id*. (the right to request access EMA documents is limited to "natural or legal persons having their registered office in an EU Member State"). Additionally, the EMA's policy against processing non-EU requests predates the GMP Report.

Further, even in the unlikely event that the EMA were to entertain a request from Plaintiffs for public access to and the release of the GMP Report, there is no

guaranty that the EMA would grant public access to the document, in whole or in part. Policy/0043 provides for a case-by-case review of requested EMA-generated documents, redaction of commercial confidential information, and/or a determination of continued no access status. In light of the EMA's discretion in granting or denying requests for public access, and the agency's declination to entertain such requests from outside the European Union, neither the Court nor Plaintiffs can predict with any certainty that a request for public access to the GMP Report would be granted were it made.

To the contrary, additional information underscores the non-public nature of the GMP Reports which reinforces the unlikelihood that the EMA would grant a request for public access. In 2017, the FDA and the EMA entered into a *Statement of Authority and Confidentiality Commitment from the United States Food and Drug Administration Not to Publicly Disclose Non-Public Information Shared by the European Commission's Directorate-General for Health and Food Safety and the European Medicines Agency ("*Confidentiality Commitment*"),* attached as Exhibit D. The Confidentiality Commitment, and the EMA counterpart agreement, attached as Exhibit E, permit the FDA and its counterpart agencies in the European Union to share and rely upon otherwise non-public information from their respective agencies in order to cooperatively perform their regulatory mandated obligations.

Importantly, the Confidentiality Commitment and its counterpart stipulate that they do not create any rights of access to non-public information which the cooperating agencies, respectively, consider confidential and non-public. Ex. D at p. 1. This stipulation precludes any notion that sharing of the GMP Report between the EMA and the FDA, if it occurred at all, creates, either inherently or explicitly, a right of public access through any Freedom of Information Act or similar request.

Further, the FDA affirmed in the Confidentiality Commitment that it "will inform promptly…EMA of any effort made by judicial or legislative mandate to obtain non-public information exchanged under the terms of this [agreement]. If such judicial or legislative mandate orders disclosure of such non-public information, FDA will take all appropriate measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure". Ex. D at p. 2, ¶ 3.

Thus, in the event of a judicial order that a non-public document such as the GMP Report be disclosed to a specific party, the document still must be protected from public disclosure, i.e., treated as a restricted confidential document that must be filed under seal. Additionally, the Confidentiality Commitment and its counterpart extend to non-public facility inspection reports. *See Strengthening EU-US cooperation in medicine inspections*, European Medicines Agency,

Aug. 23, 2017, https://www.ema.europa.eu/en/news/strengthening-eu-us-cooperation-medicine-inspections, attached as Exhibit F.

For all of the reasons set forth above, the Court should maintain ECF 1189, Ex. CC, as a Restricted Confidential document.

We thank the Court for its courtesies and consideration of this letter brief.

Respectfully submitted,

/s/ Julie S. Greenberg

Julie S. Greenberg

cc: Seth A. Goldberg, Esq.
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Christopher Geddis, Esq.